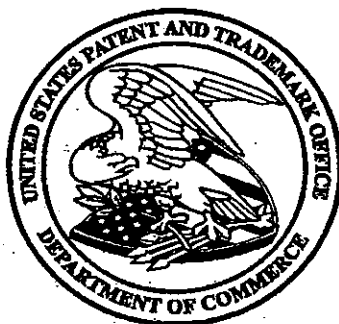


EXHIBIT H

Manual of PATENT EXAMINING PROCEDURE

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Additions to the text of the Manual are indicated by arrows (><) inserted in the text. Deletions are indicated by a single asterisk (*) where a single word was deleted and by two asterisks (**) where more than one word was deleted. The use of three or five asterisks in the body of the laws, rules, treaties, and administrative instructions indicates a portion of the law, rule, treaty, or administrative instruction which was not reproduced.

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Revision 3, August 2005
Revision 4, October 2005
Revision 5, August 2006
Revision 6, September 2007

Chapter 700 Examination of Applications

701	Statutory Authority for Examination	706.02(h)	Rejections Under 35 U.S.C. 102(g)
702	Requisites of the Application	706.02(i)	Form Paragraphs for Use in Rejections Under 35 U.S.C. 102
702.01	Obviously Informal Cases	706.02(j)	Contents of a 35 U.S.C. 103 Rejection
703	"General Information Concerning Patents"	706.02(k)	Provisional Rejection (Obviousness) Under 35 U.S.C. *103 >Using Provisional Prior Art Under 35 U.S.C. 102(e)<
704	Search and Requirements for Information	706.02(l)	Rejections Under 35 U.S.C. 103(a) Using Prior Art Under Only 35 U.S.C. 102(e), (f), or (g)
704.01	Search	706.02(l)(1)	Rejections Under 35 U.S.C. 103(a) Using Prior Art Under 35 U.S.C. 102(e), (f), or (g); Prior Art Disqualification Under 35 U.S.C. 103(c)
704.10	Requirements for Information	706.02(l)(2)	Establishing Common Ownership or Joint Research Agreement
704.11	What Information May Be Required	706.02(l)(3)	Examination Procedure with Respect to 35 U.S.C. 103(c)
704.11(a)	Examples of Information Reasonably Required	706.02(m)	Form Paragraphs for Use in Rejections Under 35 U.S.C. 103
704.11(b)	When May a Requirement for Information Be Made	706.02(n)	Biotechnology Process Applications; 35 U.S.C. 103(b)
704.12	Replies to a Requirement for Information	706.03	Rejections Not Based on Prior Art
704.12(a)	Relationship of Requirement for Information to Duty of Disclosure	706.03(a)	Rejections Under 35 U.S.C. 101
704.12(b)	What Constitutes a Complete Reply	706.03(b)	Barred by Atomic Energy Act
704.12(c)	Treatment of an Incomplete Reply	706.03(c)	Rejections Under 35 U.S.C. 112, First Paragraph
704.13	Time Periods for Reply	706.03(d)	Rejections Under 35 U.S.C. 112, Second Paragraph
704.14	Making a Requirement for Information	706.03(k)	Duplicate Claims
704.14(a)	Format of the Requirement	706.03(m)	Nonelected Inventions
704.14(b)	Examiner's Obligation Following Applicant's Reply	706.03(o)	New Matter
704.14(c)	Petitions to Requirements Under 37 CFR 1.105	706.03(s)	Foreign Filing Without License
704.14(d)	Relationship to Information Disclosure Statements	706.03(u)	Disclaimer
705	Patentability Reports	706.03(v)	After Interference or Public Use Proceeding
705.01	Instructions re Patentability Reports	706.03(w)	<i>Res Judicata</i>
705.01(a)	Nature of P.R., Its Use and Disposal	706.03(x)	Reissue
705.01(b)	Sequence of Examination	706.04	Rejection of Previously Allowed Claims
705.01(c)	Counting and Recording P.R.s	706.05	Rejection After Allowance of Application
705.01(d)	Duplicate Prints of Drawings	706.06	Rejection of Claims Copied From Patent
705.01(e)	Limitation as to Use	706.07	Final Rejection
705.01(f)	Interviews With Applicants	706.07(a)	Final Rejection, When Proper on Second Action
706	Rejection of Claims	706.07(b)	Final Rejection, When Proper on First Action
706.01	Contrasted With Objections	706.07(c)	Final Rejection, Premature
706.02	Rejection on Prior Art	706.07(d)	Final Rejection, Withdrawal of, Premature
706.02(a)	Rejections Under 35 U.S.C. 102(a), (b), or (e); Printed Publication or Patent	706.07(e)	Withdrawal of Final Rejection, General
706.02(b)	Overcoming a 35 U.S.C. 102 Rejection Based on a Printed Publication or Patent	706.07(f)	Time for Reply to Final Rejection
706.02(c)	Rejections Under 35 U.S.C. 102(a) or (b); Knowledge by Others or Public Use or Sale	706.07(g)	Transitional After-Final Practice
706.02(d)	Rejections Under 35 U.S.C. 102(c)	706.07(h)	Request for Continued Examination (RCE) Practice
706.02(e)	Rejections Under 35 U.S.C. 102(d)		
706.02(f)	Rejections Under 35 U.S.C. 102(e)		
706.02(f)(1)	Examination Guidelines for Applying References Under 35 U.S.C. 102(e)		
706.02(f)(2)	Provisional Rejections Under 35 U.S.C. 102(e); Reference Is a Copending U.S. Patent Application		
706.02(g)	Rejections Under 35 U.S.C. 102(f)		

MANUAL OF PATENT EXAMINING PROCEDURE

707 Examiner's Letter or Action

- 707.01 Primary Examiner Indicates Action for New Assistant
- 707.02 Applications Up for Third Action and 5-Year Applications
- 707.05 Citation of References
- 707.05(a) Copies of Cited References
- 707.05(b) Citation of Related Art and Information by Applicants
- 707.05(c) Order of Listing
- 707.05(d) Reference Cited in Subsequent Actions
- 707.05(e) Data Used in Citing References
- 707.05(f) Effective Dates of Declassified Printed Matter
- 707.05(g) Incorrect Citation of References
- 707.06 Citation of Decisions, Orders Memorandums, and Notices
- 707.07 Completeness and Clarity of Examiner's Action
 - 707.07(a) Complete Action on Formal Matters
 - 707.07(b) Requiring New Oath
 - 707.07(c) Draftsperson's Requirement
 - 707.07(d) Language To Be Used In Rejecting Claims
 - 707.07(e) Note All Outstanding Requirements
 - 707.07(f) Answer All Material Traversed
 - 707.07(g) Piecemeal Examination
 - 707.07(h) Notify of Inaccuracies in Amendment
 - 707.07(i) Each Claim To Be Mentioned in Each Office Action
 - 707.07(j) State When Claims Are Allowable
 - 707.07(k) Numbering Paragraphs
 - 707.07(l) Comment on Examples
- 707.08 Reviewing and Initialing by Assistant Examiner
- 707.09 Signing by Primary or Other Authorized Examiner
- 707.10 Entry
- 707.11 Date
- 707.12 Mailing
- 707.13 Returned Office Action
- 708 Order of Examination**
 - 708.01 List of Special Cases
 - 708.02 Petition To Make Special
 - 708.02(a) Accelerated Examination
 - 708.03 Examiner Tenders Resignation
- 709 Suspension of Action**
 - 709.01 Overlapping Applications by Same Applicant or Owned by Same Assignee
- 710 Period for Reply**
 - 710.01 Statutory Period
 - 710.01(a) Statutory Period, How Computed
 - 710.02 Shortened Statutory Period and Time Limit Actions Computed

- 710.02(b) Shortened Statutory Period: Situations in Which Used
- 710.02(c) Specified Time Limits: Situations In Which Used
- 710.02(d) Difference Between Shortened Statutory Periods for Reply and Specified Time Limits
- 710.02(e) Extension of Time
- 710.04 Two Periods Running
- 710.04(a) Copying Patent Claims
- 710.05 Period Ending on Saturday, Sunday, or a Federal Holiday
- 710.06 Situations When Reply Period Is Reset or Restarted
- 711 Abandonment of Patent Application**
 - 711.01 Express or Formal Abandonment
 - 711.02 Failure To Take Required Action During Statutory Period
 - 711.02(a) Insufficiency of Reply
 - 711.02(b) Special Situations Involving Abandonment
 - 711.02(c) Termination of Proceedings
 - 711.03 Reconsideration of Holding of Abandonment; Revival
 - 711.03(a) Holding Based on Insufficiency of Reply
 - 711.03(b) Holding Based on Failure To Reply Within Period
 - 711.03(c) Petitions Relating to Abandonment
 - 711.03(d) Examiner's Statement on Petition To Set Aside Examiner's Holding
 - 711.04 Public Access to Abandoned Applications
 - 711.04(a) Pulling and Forwarding Abandoned Applications
 - 711.04(b) Ordering of Patented and Abandoned Files
 - 711.04(c) Notifying Applicants of Abandonment
 - 711.05 Letter of Abandonment Received After Application is Allowed
 - 711.06 Abstracts, Abbreviations, and Defensive Publications
 - 711.06(a) Citation and Use of Abstracts, Abbreviations, and Defensive Publications as References
- 713 Interviews**
 - 713.01 General Policy, How Conducted
 - 713.02 Interviews Prior to First Official Action
 - 713.03 Interview for "Sounding Out" Examiner Not Permitted
 - 713.04 Substance of Interview Must Be Made of Record
 - 713.05 Interviews Prohibited or Granted, Special Situations
 - 713.06 No Inter Partes Questions Discussed Ex Parte
 - 713.07 Exposure of Other Cases
 - 713.08 Demonstration, Exhibits, Models

EXAMINATION OF APPLICATIONS

713.09	Finally Rejected Application	715.01	37 CFR 1.131 Affidavits Versus 37 CFR 1.132 Affidavits
713.10	Interview Preceding Filing Amendment Under 37 CFR 1.312	715.01(a)	Reference Is a Joint Patent or Published Application to Applicant and Another
714	Amendments, Applicant's Action	715.01(b)	Reference and Application Have Common Assignee
714.01	Signatures to Amendments	715.01(c)	Reference Is Publication of Applicant's Own Invention
714.01(a)	Unsigned or Improperly Signed Amendment	715.01(d)	Activities Applied Against the Claims
714.01(c)	Signed by Attorney or Agent Not of Record	715.02	How Much of the Claimed Invention Must Be Shown, Including the General Rule as to Generic Claims
714.01(d)	Amendment Signed by Applicant but Not by Attorney or Agent of Record	715.03	Genus-Species, Practice Relative to Cases Where Predictability Is in Question
714.01(e)	Amendments Before First Office Action	715.04	Who May Make Affidavit or Declaration; Formal Requirements of Affidavits and Declarations
714.02	Must Be Fully Responsive	715.05	U.S. Patent or Application Publication Claiming Same Invention
714.03	Amendments Not Fully Responsive, Action To Be Taken	715.07	Facts and Documentary Evidence
714.03(a)	Supplemental Amendment	715.07(a)	Diligence
714.04	Claims Presented in Amendment With No Attempt To Point Out Patentable Novelty	715.07(b)	Interference Testimony Sometimes Used
714.05	Examiner Should Immediately Inspect	715.07(c)	Acts Relied Upon Must Have Been Carried Out in This Country or a NAFTA or WTO Member Country
714.06	Amendments Sent to Wrong Technology Center	715.07(d)	Disposition of Exhibits
714.07	Amendments Not in Permanent Ink	715.08	Passed Upon by Primary Examiner
714.10	Claims Added in Excess of Claims Previously Paid For	715.09	Seasonable Presentation
714.11	Amendment Filed During Interference Proceedings	715.10	Review of Affidavit or Declaration for Evidence of Prior Public Use or Sale or Failure to Disclose Best Mode
714.12	Amendments and other Replies After Final Rejection or Action	716	Affidavits or Declarations Traversing Rejections, 37 CFR 1.132
714.13	Amendments and other Replies After Final Rejection or Action, Procedure Followed	716.01	Generally Applicable Criteria
714.14	Amendments After Allowance of All Claims	716.01(a)	Objective Evidence of Nonobviousness
714.15	Amendment Received in Technology Center After Mailing of Notice of Allowance	716.01(b)	Nexus Requirement and Evidence of Nonobviousness
714.16	Amendment After Notice of Allowance, 37 CFR 1.312	716.01(c)	Probative Value of Objective Evidence
714.16(a)	Amendments Under 37 CFR 1.312, Copied Patent Claims	716.01(d)	Weighing Objective Evidence
714.16(b)	Amendments Under 37 CFR 1.312 Filed With a Motion Under 37 CFR 41.208	716.02	Allegations of Unexpected Results
714.16(c)	Amendments Under 37 CFR 1.312, Additional Claims	716.02(a)	Evidence Must Show Unexpected Results
714.16(d)	Amendments Under 37 CFR 1.312, Handling	716.02(b)	Burden on Applicant
714.16(e)	Amendments Under 37 CFR 1.312, Entry in Part	716.02(c)	Weighing Evidence of Expected and Unexpected Results
714.17	Amendment Filed After the Period for Reply Has Expired	716.02(d)	Unexpected Results Commensurate in Scope With Claimed Invention
714.18	Entry of Amendments	716.02(e)	Comparison With Closest Prior Art
714.19	List of Amendments, Entry Denied	716.02(f)	Advantages Disclosed or Inherent
714.20	List of Amendments Entered in Part	716.02(g)	Declaration or Affidavit Form
714.21	Amendments Inadvertently Entered, No Legal Effect	716.03	Commercial Success
714.25	Discourtesy of Applicant or Attorney	716.03(a)	Commercial Success Commensurate in Scope With Claimed Invention
715	Swearing Back of Reference — Affidavit or Declaration Under 37 CFR 1.131		

701

MANUAL OF PATENT EXAMINING PROCEDURE

- 716.03(b) Commercial Success Derived From Claimed Invention
- 716.04 Long-Felt Need and Failure of Others
- 716.05 Skepticism of Experts
- 716.06 Copying
- 716.07 Inoperability of References
- 716.08 Utility and Operability of Applicant's Disclosure
- 716.09 Sufficiency of Disclosure
- 716.10 Attribution
- 718 Affidavit or Declaration to Disqualify Commonly Owned Patent or Published Application as Prior Art, 37 CFR 1.130**
- 719 File Wrapper**
 - 719.01 Papers in File Wrapper
 - 719.01(a) Arrangement of Papers in File Wrapper
 - 719.01(b) Prints
 - 719.02 Data Entered on File Wrapper
 - 719.02(b) Name or Residence of Inventor or Title Changed
 - 719.03 Classification During Examination
 - 719.04 Index of Claims
 - 719.05 Field of Search
 - 719.06 Foreign Filing Dates
 - 719.07 Related Applications
- 720 Public Use Proceedings**
 - 720.01 Preliminary Handling
 - 720.02 Examiner Determination of *Prima Facie* Showing
 - 720.03 Preliminary Hearing
 - 720.04 Public Use Proceeding Testimony
 - 720.05 Final Decision
- 724 Trade Secret, Proprietary, and Protective Order Materials**
 - 724.01 Completeness of the Patent File Wrapper
 - 724.02 Method of Submitting Trade Secret, Proprietary, and/or Protective Order Materials
 - 724.03 Types of Trade Secret, Proprietary, and/or Protective Order Materials Submitted Under MPEP § 724.02
 - 724.04 Office Treatment and Handling of Materials Submitted Under MPEP § 724.02
 - 724.04(a) Materials Submitted in an Application Covered by 35 U.S.C. 122
 - 724.04(b) Materials Submitted in Reissue Applications Open to the Public Under 37 CFR 1.11(b)
 - 724.04(c) Materials Submitted in Reexamination File, Open to the Public Under 37 CFR 1.11(d)
 - 724.05 Petition To Expunge Information or Copy of Papers in Application File
 - 724.06 Handling of Petitions to Expunge Information or Copy of Papers in Application File

701 Statutory Authority for Examination*35 U.S.C. 131. Examination of application.*

The Director shall cause an examination to be made of the application and the alleged new invention; and if on such examination it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor.

The main conditions precedent to the grant of a patent to an applicant are set forth in 35 U.S.C. 101, 102 and 103.

35 U.S.C. 101. Inventions patentable.

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Form paragraph 7.04 copies 35 U.S.C. 101. See MPEP § 706.03(a).

35 U.S.C. 100. Definitions.

When used in this title unless the context otherwise indicates -

- (a) The term "invention" means invention or discovery.
- (b) The term "process" means process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.
- (c) The terms "United States" and "this country" mean the United States of America, its territories and possessions.
- (d) The word "patentee" includes not only the patentee to whom the patent was issued but also the successors in title to the patentee.
- (e) The term "third-party requester" means a person requesting ex parte reexamination under section 302 or *inter partes* reexamination under section 311 who is not the patent owner.

702 Requisites of the Application [R-3]

When a new application is assigned in the Technology Center, the examiner should review the contents of the application to determine if the application meets the requirements of 35 U.S.C. 111(a). Any matters affecting the filing date or abandonment of the application, such as lack of an oath or declaration, filing fee, or claims should be checked **. For Image File Wrapper (IFW) processing, see IFW Manual sections 3.1 and 3.3.

The examiner should be careful to see that the application meets all the requisites set forth in MPEP Chapter 600 both as to formal matters and as to the completeness and clarity of the disclosure. If all of the requisites are not met, applicant may be called upon

EXAMINATION OF APPLICATIONS

716.02(g)

tive effectiveness over all compounds of the closest prior art. An applicant does not have to test all the compounds taught by each reference, “[h]owever, where an applicant tests less than all cited compounds, *the test must be sufficient to permit a conclusion respecting the relative effectiveness of applicant’s claimed compounds and the compounds of the closest prior art.*” *Id.* (quoting *In re Payne*, 606 F.2d 303, 316, 203 USPQ 245, 256 (CCPA 1979)) (emphasis in original).).

>

III. < THE CLAIMED INVENTION MAY BE COMPARED WITH THE CLOSEST SUBJECT MATTER THAT EXISTS IN THE PRIOR ART

Although evidence of unexpected results must compare the claimed invention with the closest prior art, applicant is not required to compare the claimed invention with subject matter that does not exist in the prior art. *In re Geiger*, 815 F.2d 686, 689, 2 USPQ2d 1276, 1279 (Fed. Cir. 1987) (Newman, J., concurring) (Evidence rebutted *prima facie* case by comparing claimed invention with the most relevant prior art. Note that the majority held the Office failed to establish a *prima facie* case of obviousness.); *In re Chapman*, 357 F.2d 418, 148 USPQ 711 (CCPA 1966) (Requiring applicant to compare claimed invention with polymer suggested by the combination of references relied upon in the rejection of the claimed invention under 35 U.S.C. 103 “would be requiring comparison of the results of the invention with the results of the invention.” 357 F.2d at 422, 148 USPQ at 714.).

716.02(f) Advantages Disclosed or Inherent

The totality of the record must be considered when determining whether a claimed invention would have been obvious to one of ordinary skill in the art at the time the invention was made. Therefore, evidence and arguments directed to advantages not disclosed in the specification cannot be disregarded. *In re Chu*, 66 F.3d 292, 298-99, 36 USPQ2d 1089, 1094-95

(Fed. Cir. 1995) (Although the purported advantage of placement of a selective catalytic reduction catalyst in the bag retainer of an apparatus for controlling emissions was not disclosed in the specification, evidence and arguments rebutting the conclusion that such placement was a matter of “design choice” should have been considered as part of the totality of the record. “We have found no cases supporting the position that a patent applicant’s evidence or arguments traversing a § 103 rejection must be contained within the specification. There is no logical support for such a proposition as well, given that obviousness is determined by the totality of the record including, in some instances most significantly, the evidence and arguments proffered during the give-and-take of *ex parte* patent prosecution.” 66 F.3d at 299, 36 USPQ2d at 1095.). See also *In re Zenitz*, 333 F.2d 924, 928, 142 USPQ 158, 161 (CCPA 1964) (evidence that claimed compound minimized side effects of hypotensive activity must be considered because this undisclosed property would inherently flow from disclosed use as tranquilizer); *Ex parte Sasajima*, 212 USPQ 103, 104 - 05 (Bd. App. 1981) (evidence relating to initially undisclosed relative toxicity of claimed pharmaceutical compound must be considered).

The specification need not disclose proportions or values as critical for applicants to present evidence showing the proportions or values to be critical. *In re Saunders*, 444 F.2d 599, 607, 170 USPQ 213, 220 (CCPA 1971).

716.02(g) Declaration or Affidavit Form

“The reason for requiring evidence in declaration or affidavit form is to obtain the assurances that any statements or representations made are correct, as provided by 35 U.S.C. 25 and 18 U.S.C. 1001.” Permitting a publication to substitute for expert testimony would circumvent the guarantees built into the statute. *Ex parte Gray*, 10 USPQ2d 1922, 1928 (Bd. Pat. App. & Inter. 1989). Publications may, however, be evidence of the facts in issue and should be considered to the extent that they are probative.